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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID GREWE and DAVID C. MAJERCAK

Appeal 2008-4373[1]
Application 10/691,823
Technology Center 3700

Decided: December 9, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a steerable guidewire with a deflectable tip. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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[1] Oral argument was heard in this case on November 6, 2008.

STATEMENT OF THE CASE

The Specification discloses "a steerable guidewire having improved torque characteristics, and . . . a tip which may be very precisely 'steered,' and deflected" (Spec. 1). The guidewire can be used to aid in inserting "a catheter into a vessel of the body, or alternatively, the guidewire may be used by itself to open obstructions within a vessel or to carry a therapeutic device for removing obstructions within a vessel" (*id.*).

Claims 1, 3-19, 21-23, and 25-37 stand rejected and are on appeal (App. Br. 2).[2] Claim 1 is illustrative of the claimed subject matter and reads as follows:

> 1. A bi-directional steerable guidewire having a deflectable tip which comprises:
>
> an elongated flexible tubing having proximal and distal portions;
>
> a flexible helical coil having multiple turns and having proximal and distal ends, said helical coil having a rectangular cross-sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil, the proximal end of said helical coil is attached to the distal portion of the flexible tubing;
>
> said undulations are lateral to the length of the elongated flexible tubing;
>
> said undulations taking the form of a sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns;
>
> an elongated deflection member having proximal and distal portions and being slidably disposed within said tubing and within said helical coil, the distal portion of said deflection

[2] Appeal Brief filed October 2, 2007.

member being flattened to form a deflection ribbon which extends in a plane;

a retaining ribbon for the steerable guidewire having proximal and distal ends, the proximal end of the retaining ribbon is attached to the distal portion of the flexible tubing and the retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon; and,

an attachment member for the steerable guidewire engaging the distal end of the helical coil, the distal portion of the deflection member and the distal end of the retaining ribbon so that longitudinal movement of the deflection member in a distal direction causes the distal end of the helical coil to be deflected in one direction and longitudinal movement of the deflection member in a proximal direction causes the distal end of the helical coil to deflect in another opposite direction.

The Examiner cites the following documents as evidence of unpatentability:

Hayzelden	US 2002/0165534 A1	Nov. 7, 2002
Klima	US 6,273,876 B1	Aug. 14, 2001

The following rejection is before us for review:

Claims 1, 3-19, 21-23, and 25-37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hayzelden and Klima (Ans. 3-8).

OBVIOUSNESS

ISSUE

The Examiner finds that Hayzelden discloses a bi-directional steerable guidewire for intravascular use that meets all of the claim limitations

except for expressly disclosing the helical coil having a rectangular cross-sectional configuration and having continuous undulations, wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the

> coil and wherein the undulations take the form of a sinusoidal wave and a square sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns; wherein the helical coil has a square cross-sectional configuration; the proximal end of said helical coil is attached to the distal portion of the flexible tubing; and wherein said undulations are lateral to the length of the elongated flexible tubing.

(Ans. 7.)

The Examiner cites Klima as disclosing "an intravascular device" that meets the limitations not taught by Hayzelden (*see id.* at 7-8). The Examiner concludes that, given the two references' teachings, a person of ordinary skill in the art would have considered it obvious "to modify the intravascular device as taught by Hayzelden et al, with the helical coil configuration as taught by Klima et al for the purpose of and to achieve the predictable results of increasing the efficacy of an intravascular device to navigate tortuous vasculature" (*id.* at 8).

Appellants contend, among other things, that the Examiner erred in finding that Klima meets the claim limitation requiring the positive peaks of the turns of the helical coil to "engage the negative peaks of adjacent turns" (App Br. 9, 12).

Given the arguments advanced by Appellants and the Examiner, we regard the critical issue with respect to this rejection as being whether the Examiner erred in finding that Klima meets the limitation requiring the claimed guidewire to have a helical coil with "undulations taking the form of a sinusoidal wave having positive and negative peaks . . . in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns."

FINDINGS OF FACT ("FF")

1. Claims 1, 19, and 23 are the appealed independent claims.

2. Claim 1 recites a bi-directional steerable guidewire that has a flexible helical coil with continuous interlocking undulations that "tak[e] the form of a sinusoidal wave having positive and negative peaks . . . in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns."

3. Claim 19 recites a guidewire similar to that of claim 1. Claim 19 also recites that the guidewire has a flexible helical coil with "undulations taking the form of a sinusoidal wave having positive and negative peaks . . . in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns."

4. Claim 23 recites a similar guidewire with a flexible helical coil, and also recites the same limitation as in claims 1 and 19 regarding the engagement of the positive and negative peaks of the coil's undulations.

5. Klima discloses a catheter for use in cardiovascular or neurological procedures (Klima, col. 1, ll. 20-45).

6. Klima discloses that when a physician advances a catheter into a patient, the physician "may twist a proximal end of the catheter in order to cause a corresponding twist of the distal end of the catheter (referred to as 'torque transmission response'). A consistently reliable torque transmission response (e.g., a consistent one-to-one torque transmission response) is desired" (Klima, col. 1, ll. 45-50).

7. Klima discloses that, while it is also desirable for catheters used in neurological procedures to be highly flexible, "flexibility should be attained

while retaining burst strength and without undue sacrifice of torque transmission response" (Klima, col. 1, ll. 63-65).

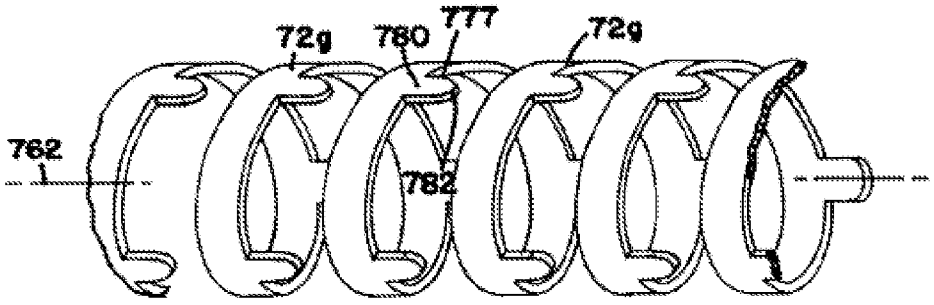
8. To meet the objectives of flexibility, strength, and adequate torque response, Klima discloses a catheter that "includes a plurality of circumferential supports surrounding the longitudinal axis. Axial members are connected to the circumferential supports. The axial members extend in a direction generally along the longitudinal axis [of the catheter] and include free ends positioned between the circumferential supports" (Klima, col. 2, ll. 16-21).

9. Klima discloses that the circumferential supports of the catheter are essentially a series of spaced adjacent rings, preferably made from medical grade stainless steel tubing, the spacing between the rings allowing for flexibility in the catheter (Klima, col. 4, ll. 5-64; *see also* Figure 3). The serial-ringed support structure surrounds a flexible tubular inner layer (*id.* at col. 3, l. 62, through col. 4, l. 3), and is covered by an outer polymer jacket of flexible material such as nylon or urethane (*id.* at col. 4, ll. 11-16).

10. In a number of embodiments the circumferential supports of Klima's catheter are provided in the form of a helical coil (*see* Klima, Figure 11A through Figure 15).

11. Figure 11B of Klima is reproduced below:

FIG. 11B



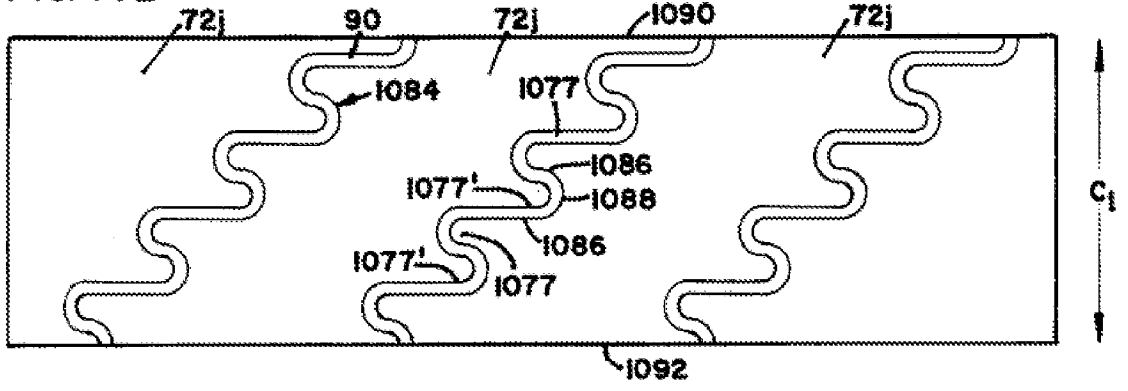
> Klima describes Figure 11 B as follows:
>
> Referring to FIG. **11**B, the circumferential supports **72***g* are shown as interconnected helical rings that wrap or extend around a longitudinal axis **762**. Axial projections **777** extend distally outward from distal ends of the circumferential supports **72***g*. The axial projections **777** are aligned parallel to the longitudinal axis **762** and include base ends **780** integrally connected to the circumferential supports **72***g* and free ends **782** positioned between the circumferential supports **72***g*. The free ends **782** of the circumferential support **72***g* are rounded.

(Klima, col. 9, ll. 21-30.)

12. To meet the claim limitation requiring the helical coil to have sinusoidal wave undulations in which positive peaks of adjacent turns engage negative peaks of adjacent turns, the Examiner cites column 11, lines 26-30, of Klima (Ans. 8, 11). The portion of Klima cited by the Examiner describes the embodiment shown in Figure 14B.

13. Figure 14B of Klima is reproduced below:

FIG. 14B



> Klima describes Figure 14B as follows:
>
> FIG. **14B** is a plan view of the catheter segment **1060**. In FIG. **14B**, the catheter segment **1060** has been longitudinally

> cut and laid flat with the inner liner **62** removed to reveal the serpentine slot **1084**. The catheter segment **1060** has a circumference C_1. When uncut, edge **1090** is intregally [sic] connected with edge **1092**.
>
> Referring back to FIG. **14B**, the longitudinal and circumferential portions **1086** and **1088** of the serpentine slot **1084** cooperate to form proximal and axial projections or fingers **1077'** and **1077** that extend longitudinally outward from the circumferential supports **72*j***. The proximal fingers **1077'** fit between and axially overlap the axial fingers **1077** of adjacent circumferential supports **72*j***. The fingers **1077'** and **1077** are separated by the portion of the flexible outer jacket **90** that fills the serpentine slot **1084**.
>
> The catheter segment **1060** utilizes circumferential supports **72*j*** having a helical coil structure to resist kinking. The interlocking axial fingers **1077** and **1077'** help to improve the torsional and axial stiffness of the catheter segment **1060**. For example, when torque is applied to the catheter segment **1060**, the fingers **1077** and **1077'** from one circumferential support **72*j*** interlock with the fingers **1077** and **1077'** from the adjacent circumferential support to inhibit relative rotation between the supports **72*j***. Consequently, torque is transmitted through the structure of the catheter segment rather than being absorbed by the deformation of the helical circumferential support structure. Substantially the same action occurs when an axial load is applied to the catheter segment **1060**. For example, the axial fingers or teeth **1077** and **1077'** prevent the circumferential supports **72*k*** from moving relative to one another thereby inhibiting the catheter segment from decreasing in diameter and inhibiting stretching of the catheter segment.

(Klima, col. 11, ll. 7-40.)

PRINCIPLES OF LAW

"[O]bviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

Thus, although the Supreme Court has emphasized the importance of a flexible approach to the obviousness question, the Court has nonetheless noted that the analysis requires a determination of "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-41 (2007) (emphasis added).

Moreover, when evaluating claims for obviousness, "the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill." *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986). It is therefore "'impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.'" *Id.* (quoting *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965)).

During examination, the PTO must interpret terms in a claim using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

ANALYSIS

We agree with Appellants that the Examiner erred in finding that Klima meets the limitation requiring the claimed guidewire to have a helical coil with "undulations taking the form of a sinusoidal wave having positive and negative peaks . . . in which the positive peaks of adjacent turns of coils

engage negative peaks of adjacent turns." Because independent claims 1, 19, and 23 recite that the positive and negative peaks of adjacent undulations must "engage" each other (FF 2-4), claims 1, 19, and 23 do not encompass structures in which adjacent peaks are separated from each other.

Klima discloses that its catheter has "circumferential supports . . . having a helical coil structure to resist kinking" (Klima, col. 11, ll. 22-23 (FF 13)). Klima describes the undulations between the adjacent turns of the helical coil as being "interlocking axial fingers **1077** and **1077'** [which] help to improve the torsional and axial stiffness of the catheter segment **1060**" (Klima, col. 11, ll. 24-25; *see also* Figure 14B (FF 13)). As the Examiner points out, Klima discloses that "when torque is applied to the catheter segment **1060**, the fingers **1077** and **1077'** from one circumferential support **72***j* interlock with the fingers **1077** and **1077'** from the adjacent circumferential support to inhibit relative rotation between the supports **72***j*" (Klima, col. 11, ll. 26-30; *see also* Figure 14B (FF 13)).

However, Klima also discloses that the finger structures are separated from each other. Specifically, Klima discloses that "[t]he fingers **1077'** and **1077** are separated by the portion of the flexible outer jacket **90** that fills the serpentine slot **1084**" (Klima, col. 11, ll. 19-21, *see also* Figure 14B (FF 13)). Thus, rather than providing an engagement between the positive and negative peaks of adjacent turns in the helical coil, as required in the appealed independent claims (*see* FF 1-3), the finger structures of Klima's helical coil engage the polymeric material of the outer jacket (*see* FF 9) that fills the slot separating the fingers.

Therefore, even when the claims are given their broadest reasonable interpretation consistent with the Specification, and even assuming for

argument's sake that one of ordinary skill would have been prompted to use Klima's supportive structure on Hayzelden's device, we agree with Appellants that the Examiner has not shown that Klima meets the limitation requiring the claimed guidewire to have a helical coil with "undulations taking the form of a sinusoidal wave having positive and negative peaks . . . in which the positive peaks of adjacent turns of coils *engage* negative peaks of adjacent turns" (emphasis added).

The Examiner does not point to, nor do we see, any other disclosures in either Klima or Hayzelden that teaches or suggests the limitation at issue. Because we agree with Appellants that the Examiner has not shown that the cited prior art teaches or suggests all of the limitations in independent claims 1, 19, and 23, we reverse the Examiner's obviousness rejection of those claims, and their dependents.

SUMMARY

We reverse the Examiner's rejection of claims 1, 3-19, 21-23, and 25-37 under 35 U.S.C. § 103(a) as being unpatentable over Hayzelden and Klima.

REVERSED

Ssc:

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